K010972 p1/3

JUN 1 2 2001

510(k) Summary

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Lisa A. Gilman
(508) 880-8287

DATE PREPARED: May 8, 2001

CLASSIFICATION NAME: Spinal interlaminal fixation orthosis, §888.3050
Pedicle screw spinal fixation §888.3070

PROPRIETARY NAME: ISOLA Band Clamp

PREDICATE DEVICES: The ISOLA Band Clamp is substantially equivalent to ISOLA Slotted Connector cleared in 510(k) K980485 and the Anterior ISOLA System cleared in 510(k) K943819 and K993030.

DEVICE DESCRIPTION: The ISOLA Band Clamp is a one-piece offset connector for use when the rod and screw are in close proximity to each other. The body of the band clamp accepts a 6.35mm rod. The band clamp sits on the integral nut portion of the pedicle screw and the rod is secured in place by tightening down the top nut of the pedicle screw.

INTENDED USE: The indications for use for the modified device described in this submission are the same as those for the ISOLA System cleared in 510(k) K980485 and the Anterior ISOLA System cleared in 510(k) K943819. The indications are as follows:

The Posterior ISOLA System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA System and TiMX Low Back System, when used with pedicle screws, is indicated for degenerative spodylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA System and TiMX Low Back System are also indicated for pedicle screw fixation for Grade 3 and 4 spondylolisthesis at L5-S1, in skeletally mature patients, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

The Posterior ISOLA Spinal System and TiMX Low Back System, when not used with pedicle screws, are intended for posterior hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed fusion.

The Anterior ISOLA system is intended for use in correcting scoliotic, lordotic or kyphotic spinal deformities by establishing an axially and rotationally rigid fixation bridge parallel to the long axis of the spine. The system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present. Spinal levels for anterior ISOLA instrumentation are from T5-L4.

Properly used, the Posterior and Anterior ISOLA Systems and the TiMX Low Back System will provide temporary stabilization as an adjunct to spinal bone grafting processes. Specific indications are:

1. Idiopathic scoliosis

2. Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.

3. Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.

4. Spinal fractures (acute reduction or late deformity).

5. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).

6. Spondylolisthesis.

7. Neoplastic disease.

8. Previously failed fusion.

The Anterior ISOLA system is also used for the correction and stabilization of scoliotic curves, for the prevention or recurrence of undesired scoliotic curves, and for the stabilization of weakened trunks. Indications for these scoliotic uses include:

1. Collapsing and unstable paralytic deformity.

2. Progressively increasing scoliosis.

3. Decreasing cardio-respiratory function, secondary to spinal or rib deformity or collapse.

4. Inability to maintain sitting balance, necessitating the use of the hands.

5. Increasing pelvic obliquity coincident with back pain or loss of sitting balance.

MATERIALS: Manufactured from ASTM F-138 implant grade stainless steel.

PERFORMANCE DATA: Performance data were submitted to characterize the ISOLA Band Clamp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2001

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K010972
Trade Name: ISOLA Band Clamps
Regulatory Number: 888.3070, 888.3070 and 888.3050
Regulatory Class: II
Product Code: MNI, KWP and MNH
Dated: May 11, 2001
Received: May 16, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010972

Device Name: ISOLA Band Clamp

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(per 21 CRF 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010972